inda Association of the
Nonwoven Fabrics Industry

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April 21, 1999

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: **Medical Devices; Labeling For Menstrual Tampons; Ranges of Absorbency (FDA Docket Number 98N-0970)**

Dear Sir or Madam:

I am writing on behalf of INDA, Association of the Nonwoven Fabrics Industry, in regard to the proposed rule "Medical Devices; Labeling For Menstrual Tampons; Ranges of Absorbency (FDA Docket Number 98N-0970)" published in the January 21, 1999 *Federal Register*. INDA commends FDA for issuing this proposed rule, and encourages the Agency to allow the sale of tampons in the 15-18 gram absorbency range as soon as possible within the United States.

INDA has several other comments related to tampon labeling requirements contained in 21 CFR 801.430 that we would also like to share, and we ask FDA to consider these as the Agency moves forward with the proposed rule.

INDA Background and Basis for Comment

INDA is the internationally-recognized trade association of the nonwoven fabrics industry. Nonwovens are a multi-billion dollar business in the United States and are used extensively in the manufacture of tampons and menstrual pads. INDA members include tampon manufacturers, fiber producers, and other producers of components used in the manufacture of tampons.

INDA has recently formed a Feminine Hygiene Task Force made up of member and non-member companies, and has asked that Task Force to review FDA's January 21 proposed rule. INDA's goal is to produce a comment that reflects areas of consensus within the participating companies on the issues raised by this proposed rule.

Members of INDA's Feminine Hygiene Task Force include representatives from: Acordis Fibers, Cotton, Inc., First Quality, Kimberly-Clark, Paragon Trade Brands, Personal Products Company, Playtex Products, Inc., and Procter & Gamble. Together, these companies account for the majority of tampons sold in the United States.

I: Absorbency Capacity of 15-18 Grams of Fluid

INDA agrees with FDA and the Federal Centers for Disease Control and Prevention (CDC) that tampons with an absorbency capacity in the range of 15-18 grams of fluid will not materially increase the risk of Toxic Shock Syndrome (TSS) for women who use tampons. As noted on Page 3255 of the January 21 notice, tampons in this absorbency range have been marketed in other countries, with very low TSS rates. Tampons with this absorbency range should, therefore, also be allowed for sale in the United States so that women with heavier rates of menstrual flow can benefit from their availability.

In addition, INDA supports FDA's proposed effective date contained in the proposed rule of 30 days after publication to be appropriate. This proposed effective date will permit U.S. sale of tampons in the 15-18 gram absorbency range as quickly as possible, a goal that INDA encourages.

Consensus does not exist, however, among members of INDA's Feminine Hygiene Task Force on the proper term that should be used to designate tampons that absorb 15-18 grams of fluid. Due to this lack of consensus, INDA anticipates that one or more of its Task Force members will file separate comments with the Agency on this aspect of the proposed rule.

It is INDA's hope that this lack of consensus will not hinder FDA's proposal, however, and that the Agency will move forward on the matter at the soonest possible date. **We urge FDA to review each of the comments received on this specific issue and determine the proper designation for tampons with an absorbency capacity of 15-18 grams as quickly as possible.**

II: Use of the Term "Junior" to Designate Tampons that Absorb Less than Six Grams of Fluid (21 CFR 801.430 (e) (1))

Since 1989, U.S. tampon manufacturers have been required to use the term "Junior" to designate tampons that absorb six grams of fluid or less. In that time, a number of Task Force members have noted that — based on the use of this term — a general consumer perception has developed such that many adult women believe these lower-absorbency "Junior" tampons are intended for use by younger women (such as teenagers) rather than for the control of lesser amounts of menstrual flow. These perceptions have repeatedly been noted in calls to consumer phone lines established by several of INDA Task Force members, as well as through market research, and in other consumer interactions.

Considering FDA's desire to have women select tampons with the minimum absorbency needed to control menstrual flow, as indicated in 21 CFR 801.430 (d)(3), INDA believes that certain adult women with very low rates of menstrual flow may unwittingly be selecting more absorbent "Regular" tampons based on their perception that "Junior" tampons are not appropriate for anyone beyond a certain age range (e.g., mid-teen years or at the onset of menarche).

INDA suggests, therefore, that a more age-neutral term be used for tampons that absorb six grams of fluid or less. Members of the Task Force, in fact, have collectively recommended that the term "Light" be substituted for the term "Junior"in the table at 21 CFR 801.430 (e) (1), and that this change be made as quickly as possible.

Manufacturers should, however, be granted sufficient time (e.g., at least one year from the date of publication of a final rule covering this point) to liquidate existing inventories of tampon packaging materials that use the absorbency term "Junior."

III: Incidence of TSS Required Under 21 CFR 801.430 (d)(2)

INDA notes that the reference to estimated incidence of TSS contained in 21 CFR 801.430 (d)(2) does not reflect the most recent statistics available from Federal Centers for Disease Control (CDC) or FDA correspondence to tampon manufacturers.

In a September 13, 1993, memorandum from Lillian L. Yin, Ph.D., Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices, Office of Device Evaluation, FDA's Center for Devices and Radiological Health, addressed to "Manufacturers of Menstrual Tampons," regarding "FDA's Position on Eight Hours/Overnight Use of Menstrual Tampons" (copy attached) it is noted that, "The incidence of menstrual TSS is estimated at 1 case per 100,000 menstrual women."

Dr. Lin cites CDC's Reviews of Infectious Diseases, Vol. 11, Supplement 1 (January-February 1989) as the basis for this estimate.

Considering that CDC and FDA both conclude that incidence of TSS is significantly less than the "1 to 17 per 100,000" figure which must be printed on package inserts under 21 CFR 801.430 (d)(2), INDA requests that this portion of the currently-required insert labeling be altered to reflect these more recent data.

INDA thanks FDA for the opportunity to file comments on the Agency's proposed rule. It is our hope that FDA will promulgate a final rule on the "Medical Devices; Labeling For

Menstrual Tampons; Ranges of Absorbency," and will act on our additional requested labeling changes as quickly as possible. Please feel free to contact me should you have any questions or need additional information regarding any aspect of these comments.

Sincerely,

Peter G. Mayberry,
Director of Government Affairs

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